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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA
ex rel. STEVE GREENFIELD et al.,

Plaintiff,

v.

MEDCO HEALTH SYSTEMS, INC.,
ACCREDITO HEALTH GROUP, INC.,
and HEMOPHILIA HEALTH
SERVICES, INC.,

Defendants.

)
)
) Civil No. 1:12-cv-00522-NLH-AMD

) **BRIEF IN SUPPORT OF**
) **MOTION FOR SUMMARY**
) **JUDGMENT**

) **Motion Date: June 6, 2016**
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)
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PRELIMINARY STATEMENT

In this non-intervened *qui tam* lawsuit, Relator Steve Greenfield (“Greenfield”) claims that Accredo, a specialty pharmacy serving hemophilia patients, violated the federal Anti-Kickback Statute (“AKS”), and that Accredo’s claims for reimbursement to Medicare and Medicaid therefore violated the False Claims Act (“FCA”).

Exhaustive discovery has shown these allegations to be without merit.

Greenfield’s Complaint principally alleges that Accredo’s charitable contributions to the Hemophilia Association of New Jersey (“HANJ”), to fund a program that purchases private insurance for needy hemophilia patients, were illegal “kickbacks” paid in return for HANJ referring federally-insured patients (“Federal Beneficiaries”) to Accredo. As discovery has revealed, there is no evidence that HANJ referred *any* patients, much less Federal Beneficiaries, to Accredo. The AKS applies only to payments for Federal Beneficiaries, but it is undisputed that HANJ’s insurance program was expressly designed to *exclude* Federal Beneficiaries. And there is no evidence of a connection between Accredo’s charitable donations to HANJ and any of Accredo’s claims for reimbursement to government healthcare programs, an absence which alone is fatal to Greenfield’s FCA claims.

The Complaint also alleges that Accredo gave items of value directly to Federal Beneficiaries in exchange for using Accredo’s services. Discovery has revealed no support for that claim, and Greenfield appears to have abandoned it altogether.

Finding no support for the claims in his Complaint, Greenfield now asserts that Accredo's contributions to HANJ were in return for (1) HANJ unlawfully "recommending" Accredo by including it on a list of approved providers, and (2) persuading HANJ to withdraw a so-called "non-recommendation" when it informed HANJ members of Accredo's decision to reduce the amount of its charitable contribution. These new theories are no better than the old ones. First, the alleged conduct does not violate the AKS; if it did, Greenfield's theory would make a federal crime of charities' typical and constitutionally protected conduct. Second, Greenfield cannot tie Accredo's charitable contributions to any claims for reimbursement that Accredo may have made to the government. He cannot show that even a single Federal Beneficiary purchased Accredo's products or services because of a contribution to HANJ.

Greenfield also cannot show that Accredo personnel had a *willful, criminal intent* to pay a kickback in exchange for Federal Beneficiaries, as the AKS requires, or that Accredo *knowingly submitted false claims* to the government, as the FCA requires. There is no evidence that Accredo made contributions to HANJ for the purpose of inducing referrals, let alone with the knowledge that its contributions were illegal. On the contrary, Accredo's contributions supported an insurance program that the State of New Jersey expressly endorsed.

There is, in short, no genuine issue of fact for trial.

STATEMENT OF THE FACTS

A. Procedural History

Relator Steve Greenfield, a former employee of Accredo,¹ filed this *qui tam* action on January 27, 2012, seeking to recover damages on behalf of the United States and multiple State governments under the federal FCA and state law analogs.

Statement of Material Facts Not in Dispute (“SMF”) ¶ 1. After conducting an investigation, the federal and state governments declined to intervene as plaintiffs. SMF ¶ 2.

On Accredo’s motion to dismiss, after once dismissing with leave to amend, the Court ultimately dismissed with prejudice Greenfield’s state law claims and his federal conspiracy claim. 9/26/14 Opinion (Dkt. 50) (“Op.”). The Court permitted Greenfield’s federal FCA claims to proceed under 31 U.S.C. § 3729(a)(1) and (a)(2)—counts 1 and 2. *See id.* In the operative Fourth Amended Complaint (the “Complaint”), Greenfield contends that Accredo violated the FCA by submitting “false” claims for reimbursement for hemophilia medication and pharmacy services provided to patients insured by Medicare and Medicaid during the period from January 1, 2008 through December 31, 2012. 4AC (Dkt. 52). The reimbursement

¹ “Accredo” refers collectively to all three Defendants: (1) the specialty pharmacy Accredo Health Group, Inc., (2) Hemophilia Health Services, Inc. (“HHS”), which was merged into Accredo in 2006, and (3) Medco Health Solutions, Inc. (incorrectly pled as “Medco Health Systems”), a pharmacy benefit management company, which in turn acquired Accredo Health Group, Inc. in 2005. SMF ¶ 12.

claims allegedly were “false” because of Accredo’s violations of a separate federal law, the AKS, which prohibits knowingly and willfully making corrupt payments in exchange for “referring” government-insured patients or in exchange for purchasing or “recommending” government-insured products or services. 4AC (Dkt. 52).

In its decision on the motion to dismiss, the Court noted that Greenfield had not alleged specific facts regarding the reimbursement claims Accredo allegedly presented to the federal government. Op. at 26–27. The Court found, however, that Greenfield had stated a claim because he alleged facts that, if proved, would show a scheme (a) to pay contributions to HANJ in return for referring patients to Accredo, and (b) to give excessive gifts to patients in exchange for purchasing Accredo’s products and services, where some of the patients in each category allegedly were Medicare and Medicaid recipients. Op. at 21 & n.9, 26.

B. Factual Background

1. Hemophilia and its treatment

Hemophilia is a rare, inherited blood disorder. SMF ¶ 7. Hemophilia patients need frequent infusions of “factor” to improve blood clotting. SMF ¶ 8. Factor is typically administered at home by the patient. SMF ¶ 9. Hemophilia patients also commonly receive outpatient care at Hemophilia Treatment Centers, or “HTCs,” which are specialized clinics associated with hospitals. SMF ¶ 7.

Accredo is a “specialty pharmacy,” which provides hemophilia patients with factor and other pharmacy services tailored to this rare condition. SMF ¶ 10. Unlike

typical walk-in pharmacies, specialty pharmacies provide services for patients with more severe or specialized needs. SMF ¶ 11.

2. Hemophilia in New Jersey

New Jersey has laws and regulations specifically designed to ensure effective treatment of hemophilia patients. SMF ¶ 20. Since 2000, insurance carriers are required to utilize only those hemophilia home care providers that comply with standards “adopted by regulation of the Department of Banking and Insurance in consultation with [HANJ].” SMF ¶¶ 20–21. Accredo is one of the state-approved providers. SMF ¶ 22.

HANJ is a charitable organization dedicated to improving the lives of persons living with hemophilia. SMF ¶ 13. HANJ has for the past 45 years advocated for and supported hemophilia patients throughout the State. *Id.*

In 1987, HANJ, at the request of the State of New Jersey, assumed responsibility for administering an insurance program that purchases private insurance for the benefit of hemophilia patients in the State who cannot otherwise afford insurance. SMF ¶ 15. Patients are eligible for the HANJ insurance program only if they do not receive Medicare or Medicaid. SMF ¶¶ 50–52.

The State of New Jersey supports the HANJ insurance program, including through monetary block grants. SMF ¶ 16. The State’s funding is not sufficient to subsidize all of HANJ’s insurance needs. *Id.* Accordingly, HANJ has for decades solicited and received private charitable donations, including from approved

hemophilia home care companies in the State of New Jersey. SMF ¶ 19. Accredo has contributed to the HANJ insurance fund. SMF ¶ 48. Accredo's contributions for this purpose are made to HANJ's affiliate Hemophilia Services, Inc. ("HSI"), which in turn donates the funds to HANJ to pay the insurance premiums. SMF ¶¶ 19, 48.

3. Greenfield's employment with Accredo

Accredo hired Greenfield in 2009 as a vice president in its sales department. SMF ¶ 31. By late 2011, Greenfield was under investigation by Accredo's human resources department for inappropriate comments and behavior in the workplace.² SMF ¶ 32. After he sought to interfere with that investigation, Accredo terminated his employment in early 2012. SMF ¶ 37. While the investigation was ongoing, Greenfield retained counsel and filed this *qui tam* lawsuit. SMF ¶¶ 33, 36.

At no time during his employment did Greenfield inform Accredo's compliance department, its legal department, or his superiors of any concern that Accredo may have violated the AKS, the FCA, or any other law. SMF ¶ 38.

C. The Evidence in Discovery

Discovery has been extensive. Accredo produced voluminous data and over 37,000 pages of documents; Greenfield also subpoenaed documents from HANJ. SMF ¶ 39. Twenty-one witnesses were deposed, including 14 current and former

² Among other things, Greenfield made a comment to a pregnant co-worker to the effect that "pregnant women are sexy," and he used a racial slur to describe Korean-Americans. SMF ¶ 32.

Accredo personnel, HANJ's Executive Director, and HANJ's former President and board member. SMF ¶ 40. Despite this substantial discovery record, Greenfield has mustered no meaningful evidence in support of his claims.

To show an AKS violation, Greenfield must prove that someone at Accredo intentionally violated the law by paying for referrals of Federal Beneficiaries. Not a single witness, including Greenfield himself, testified that anyone intended to pay for patient referrals or knowingly broke the law. *See* SMF ¶¶ 103–05. Decisionmakers at Accredo and HANJ testified to precisely the opposite: that Accredo's contributions were intended to support the HANJ insurance program (which was not for Federal Beneficiaries) and to generate goodwill in the hemophilia community. SMF ¶¶ 44–45, 161–62. Similarly, among the tens of thousands of pages of documents produced in discovery, Greenfield has identified nothing that shows a quid pro quo for patient referrals. If anything, discovery has placed into context the documents attached to Greenfield's Complaint, confirming that they do not suggest liability.

Regarding the claim that Accredo made improper payments to HANJ, Greenfield designated one expert on liability: Kevin McAnaney, a practicing attorney who purports to testify, based on his legal analysis, that “experienced health care counsel, regulators and industry participants would have reasonably concluded that the arrangement between HANJ/HSI and [Accredo] violated the AKS.” Singer Decl.

Ex. 37 (McAnaney Report at 6).³ In his deposition, McAnaney conceded that contributions made for the purpose of supporting the HANJ insurance program did not implicate the AKS because the beneficiaries were not federally insured. SMF ¶¶ 53–54. He also agreed that HANJ never made “referrals” within the meaning of the AKS. SMF ¶ 158. McAnaney’s theory of liability is that an experienced observer would perceive Accredo’s contributions to HANJ as unlawful because: (1) HANJ “recommended” Accredo, along with other home care companies, by identifying it as an “HSI approved provider” on HANJ’s website and other materials; and (2) in 2011, after first reducing its pledged contribution to HANJ, Accredo decided to restore its contribution to its prior level so that HANJ would refrain from criticizing Accredo’s charitable giving. *See* Singer Decl. Ex. 37 (McAnaney Report). In response to McAnaney’s report, Accredo disclosed (among others) a report from Thomas Crane, a prominent healthcare lawyer and former counsel to the Office of the Inspector General of the U.S. Department of Health and Human Services, who concludes that those in the industry with AKS experience would not consider Accredo’s contributions to HANJ to be unlawful. Singer Decl. Ex. 36 (Crane Report).

³ We assume, solely for purposes of this motion, that McAnaney’s opinions would be admissible at trial. As discussed below, those opinions, if admitted, would not allow this case to survive summary judgment. In the event this case proceeds to trial, Accredo anticipates moving to exclude McAnaney’s opinions in their entirety because (among other things) they are inadmissible legal opinions.

During the course of discovery, Greenfield apparently abandoned his claim that Accredo violated the law by giving items of value to patients. He offered no expert analysis on this topic.

STANDARD OF REVIEW

Summary judgment should be granted “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). When, as here, the non-moving party has the burden of proof, and the moving party identifies “sufficient facts of record to demonstrate that no genuine issue of material fact remains, the nonmoving party is obliged to identify those facts of record which would contradict the facts identified by the movant.” *Childers v. Joseph*, 842 F.2d 689, 694–95 (3d Cir. 1988).

ARGUMENT

I. THERE IS NO EVIDENCE THAT ACCREDO VIOLATED THE AKS.

Greenfield’s FCA claims depend, in the first instance, on proving that Accredo violated the AKS, a federal criminal statute. Because the undisputed evidence shows that Accredo did *not* violate the AKS, its claims were not “false” under the FCA.

The AKS makes it a crime to:

knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing . . . of any item or service for which payment

may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(2). Greenfield cannot prove either of the two central elements of an AKS violation: (1) that Accredo offered or paid anything to HANJ or any patient *to induce*—that is, in exchange for—referring *government-insured* patients or recommending the purchase of government-reimbursed products, or (2) that Accredo did so *knowingly and willfully*—that is, with the intent to violate the law. *See United States v. Goldman*, 607 F. App’x 171, 173–74 (3d Cir. 2015).

A. The AKS Does Not Prohibit Payments for Non-Government Insured Patients.

According to the Complaint, a central component of Accredo’s alleged referral scheme was to contribute to the HANJ insurance program so that the beneficiaries of that program would be referred to Accredo. 4AC ¶ 7. Greenfield alleged that HANJ’s Executive Director Elena Bostick and Accredo executive Craig Mears had a “quid pro quo arrangement” whereby Accredo “provided money to fund insurance for patients,” and HANJ demanded a certain amount of money for each such patient. 4AC ¶ 83.

Greenfield’s principal theory has fallen by the wayside, as it is uncontested that the insurance grant program existed to provide *private insurance* to individuals who were

otherwise *uninsured*. HANJ represented to homecare companies that its insurance program would not provide assistance to individuals eligible for benefits under federal health care programs, and it sought representations from applicants for grants that they were not so eligible. SMF ¶¶ 50–51.

As Greenfield’s proffered expert on liability has conceded, because the HANJ insurance program “was not available to people getting federal health benefits,” the AKS does not apply to it. Singer Decl. Ex. 34 (McAnaney Dep. at 193:12–24; 196:20–198:12; 212:8–23); SMF ¶¶ 53–54. The AKS’s prohibition extends only to patients or products “*for which payment may be made in whole or in part under a Federal health care program.*” 42 U.S.C.A. § 1320a-7b(b)(2) (emphasis added). Referrals or recommendations for goods or services paid for by private or non-Federal health care programs are entirely outside the ambit of the AKS. *See, e.g.*, Singer Decl. Ex. 71 (OIG Advisory Opinion No. 11-05 (“Because Federal health care program beneficiaries are not eligible to receive vouchers . . . the Voucher Arrangement does not implicate the [AKS].”)). Singer Decl. Ex. 71. For this reason, the OIG guidance cited prominently in the Complaint is inapplicable, as Greenfield’s expert also concedes. Singer Decl. Ex. 34 (McAnaney Dep. at 196:20–198:12; 212:8–23); SMF ¶ 54; *see also, e.g.*, Singer Decl. Ex. 35 (70 Fed. Reg. at 70624).⁴

⁴ Were OIG guidance relevant, however, the record demonstrates that the HANJ insurance program was administered in a manner consistent with each of the non-binding guidelines set forth in the 2005 OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees. SMF ¶¶ 55–73.

B. There Is No Evidence that Accredo's Contributions to HANJ Were Kickbacks for Covered Referrals or Recommendations.

1. The AKS requires intent to pay kickbacks for covered referrals or recommendations.

Even where Federal Beneficiaries are involved, the “Anti-Kickback” Statute criminalizes a limited category of arrangements. It prohibits kickbacks, bribes, or the like, whereby the perpetrator gives something of value “to induce” referrals or recommendations of covered patients or products. For a payment to implicate the AKS, it must be intended to trade for government-insured patients or products, not merely to encourage them.

The law is clear that the AKS does not criminalize referrals, nor does it criminalize business arrangements from which referrals foreseeably result. *See United States v. McClatchey*, 217 F.3d 823, 834–35 (10th Cir. 2000) (approving jury instruction to that effect); *Feldstein v. Nash Cmty. Health Servs., Inc.*, 51 F. Supp. 2d 673, 681 (E.D.N.C. 1999) (“[T]he facts that a hospital offers a physician remuneration for his services and that the physician refers patients to that hospital do not, in and of themselves, constitute a violation of the anti-kickback statute.”). Referrals are a legitimate and essential part of business, without which no service provider in the health care industry could function or compete successfully. The statute is not meant to “imped[e] legitimate and beneficial activities” or to prevent healthcare professionals from “freely engag[ing] in business practices and arrangements that encourage competition, innovation and economy.” Singer Decl. Ex. 72 (Medicare and Medicaid

Programs: Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 3089, 3093 (Jan. 23, 1989)).

The AKS therefore “does not criminalize *referrals*; rather, it criminalizes knowing and willful acceptance of remuneration in return for such referrals.” *United States ex rel. McDonough v. Symphony Diagnostic Servs., Inc.*, 36 F. Supp. 3d 773, 777 (S.D. Ohio 2014) (internal quotation marks omitted), *appeal dismissed* (Jan. 7, 2015). One may lawfully request or encourage covered referrals or recommendations, but may not buy or sell them. *See, e.g., United States v. Krikheli*, 461 F. App’x 7, 11 (2d Cir. 2012) (affirming instruction requiring proof that “the remuneration was offered or paid as a *quid pro quo* in return for the referring of the patient” (internal quotation marks omitted)); *United States v. Goss*, 96 F. App’x 365, 368 (6th Cir.) (noting prohibition on “provid[ing] referrals [of Federal health care patients] as a *quid pro quo*”), *amended on reh’g en banc*, 100 F. App’x 461 (6th Cir. 2004); *United States ex rel. Jamison v. McKesson Corp.*, 900 F. Supp. 2d 683, 699 (N.D. Miss. 2012) (concluding after a bench trial that the government failed to show any *quid pro quo*).

This requirement is embodied in the statutory term “induce,” which courts sometimes describe as “intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business.” *Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995) (internal quotation marks omitted); *see Cooper v. Pottstown Hosp. Co.*, No. 13-01137, 2015 WL 1137664, at *3 (E.D. Pa. Mar. 13, 2015) (“[T]he statute, at its core, ‘is aimed at the inducement factor.’”

(quoting *United States v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985))). That the term “induce” in 42 U.S.C. § 1320a-7b(b)(2) means an offer or payment as a quid pro quo for referrals is clear from the corresponding AKS subsection, § 1320a-7b(b)(1), which applies to those who *solicit and receive* kickbacks: that section prohibits soliciting or receiving a payment “*in return*” for covered referrals, 42 U.S.C. § 1320a-7b(b)(1) (emphasis added). “Induce” and “in return for” are two sides of the same coin. Both prohibit exchanging remuneration for referrals. *See, e.g., Robert Wood Johnson Univ. Hosp., Inc. v. Thompson*, No. Civ.A.04-142(JWB), 2004 WL 3210732, at *6 (D.N.J. Apr. 15, 2004) (“[B]ecause the Participating Hospitals do not seek—with the requisite scienter—the direct inducement of patient referrals, it does not appear that the Demonstration Project violates [the AKS].”).⁵

Thus, a defendant does not illegally induce covered referrals merely by entering into an arrangement that he hopes or expects will result in covered referrals or recommendations, as long as he is not actually *paying for* such referrals or recommendations. *See United States ex rel. Williams v. Health Mgmt. Assocs., Inc.*, No. 3:09-cv-130 (CDL), 2014 WL 2866250, at *11 (M.D. Ga. June 24, 2014); *United States v. Shaw*, 106 F. Supp. 2d 103, 120 (D. Mass. 2000). As one court explained, reciting the instructions it gave to the jury,

⁵ To be sure, the AKS prohibits corruptly-intended offers and payments even when no agreement or referral actually results. Absent a consummated agreement, however, Greenfield could not prove that any claim presented to Medicare or Medicaid resulted from an AKS violation. *See infra* Part II.A.

[e]ven if patient referrals were devoutly hoped for and anticipated; even if the volume of patients could be large; *even if the parties might never have come together but for [the defendant] having embarked on a long range plan that depended on attracting nursing home patients*, there is nothing in the evidence or the law that would have a priori precluded a legal relationship from being entered into under these circumstances.

United States v. Anderson, 85 F. Supp. 2d 1047, 1064 (D. Kan. 1999) (emphasis added) (internal quotation marks omitted), *rev'd on other grounds sub nom. United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000).

While the AKS is violated if “one purpose” of a payment is unlawful, *Greber*, 760 F.2d at 69, the “one purpose” must be a *criminal* purpose. *See United States ex rel. Ruscher v. Omnicare, Inc.*, No. 4:08-cv-3396, 2015 WL 5178074 (S.D. Tex. Sept. 3, 2015) (applying one purpose test but finding no evidence of criminal intent). Greenfield thus was obliged to produce actual evidence that Accredo offered or gave remuneration, in whole or in part, for that unlawful, criminal purpose—namely, to buy covered referrals or recommendations.

That the AKS is limited to corrupt exchanges for federal business makes it ill-suited to punish charitable contributions. Defendants are aware of *zero* reported cases finding an AKS violation based on a charitable contribution. Similarly, although it has not ruled out the possibility, *e.g.*, Singer Decl. Ex. 73 (OIG Advisory Opinion No. 10-19), the OIG has never concluded that any payment characterized as a charitable contribution raised AKS concerns. This should be unsurprising, as charities typically

do not control patients' healthcare decisions—and HANJ is no exception. *See infra* Part I.B.3.

2. The evidence shows that Accredo's charitable contributions to HANJ were made for legitimate purposes.

Greenfield bears the burden of proving that Accredo's contributions to HANJ were intended, at least in part, for the improper purpose of paying for federally insured patient referrals or recommendations. The evidence is to the contrary. Accredo's contributions were made to HANJ's insurance program, in which Federal Beneficiaries do not even participate. SMF ¶¶ 50–52. Far from an illegal vehicle for kickbacks, the HANJ insurance program is expressly endorsed by the New Jersey government, and it requires industry contributions to ensure that hemophilia patients receive necessary care. SMF ¶¶ 15–16, 19.

The legitimate reasons for Accredo to make such contributions are undisputed. Like any corporate contributor, Accredo had a business interest in fostering and preserving goodwill in the community of patients who are Accredo's customers. SMF ¶ 44; Singer Decl. Ex. 31 (Frumkin Report at 2, 13). Accredo reasonably expected that contributing to support HANJ's insurance program would generate such goodwill. SMF ¶ 161–62; Singer Decl. Ex. 31 (Frumkin Report at 13). Accredo also had a philanthropic interest in supporting HANJ's charitable mission; Accredo executives specifically wanted to prevent hemophilia patients from being “cut off” from insurance. SMF ¶¶ 47, 90, 160.

The contributions to HANJ furthered Accredo’s general policy to contribute to charitable organizations that benefit healthcare and support patient advocacy. The company considered charitable giving an important part of its overall business mission. SMF ¶ 41. Accredo thus made contributions to a wide variety of charities throughout the country. *See* SMF ¶ 42. For example, the company contributed to PSI, a Virginia-based charity that, similar to HANJ, provides insurance to patients with chronic illnesses. SMF ¶ 43.

Accredo also had two very specific business interests in ensuring that the HANJ insurance program was adequately funded. First, because the patients who received HANJ grants were, by definition, otherwise uninsured, the failure of the insurance program would have left those patients unable to pay for the medication that Accredo and other specialty pharmacies dispensed. SMF ¶ 162. Second, Accredo had an interest, peculiar to the hemophilia treatment sphere, in reducing the risk that HTC’s might adopt “340B programs,”⁶ which would have allowed the HTC’s to supply factor directly to patients, introducing a new (and advantageously placed) competitor in Accredo’s New Jersey market. SMF ¶¶ 162, 93–94.

3. Greenfield’s “kickback” theories are without merit.

All of the above reasons for contributing are lawful, and they have nothing to do with federally-insured patients. Greenfield imagines, however, that Accredo’s

⁶ “340B” refers to Section 340B of the Public Health Service Act, codified as 42 U.S.C. § 256b.

contributions to the insurance program were really in exchange for HANJ steering Federal Beneficiaries—patients who *did not benefit from Accredo’s contributions to the HSI insurance program*—to Accredo. This theory defies common sense and, as is typical of such arguments, the evidence does not support it. We address each of Greenfield’s several theories in turn below.

a. HANJ is not a referral source.

The theory that permeates Greenfield’s Complaint is that HANJ somehow referred patients to Accredo. *See, e.g.*, 4AC ¶¶ 7, 102. Discovery has proven that contention untrue. As Greenfield’s expert admits, there is no evidence that HANJ made referrals. SMF ¶ 158. Rather, characteristic of hemophilia groups nationwide, HANJ supports and advocates for the hemophilia community. SMF ¶ 101.

1) *There is no evidence that HANJ made direct referrals.*

There is no evidence in the record that HANJ ever referred patients directly to Accredo. HANJ’s Executive Director, Elena Bostick, testified unambiguously that HANJ did not make such referrals. SMF ¶ 101. To the contrary, “what we have advocated for in the State of New Jersey and continue to this day is patient choice. So what the patient chooses to select in terms of the product they use, the treatment center they are able to access, the homecare company they use, our goal is to ensure that that choice is available to him.” SMF ¶ 102.

Similarly, the Accredo personnel who decided what contributions Accredo would make uniformly testified that they had no understanding that HANJ made any referrals. SMF ¶ 103. Nor has Greenfield presented evidence from even a single patient indicating that the patient was “referred” by HANJ. SMF ¶¶ 104–05.

While Greenfield and his friend Karen Griffin testified that they *believed* HANJ could make referrals to Accredo, they offered nothing but speculation to support that belief. Neither could identify any patient that HANJ referred to Accredo. SMF ¶¶ 104–05. Greenfield admitted that “[he] didn’t speak with the patient or HANJ” about referrals. SMF ¶ 107.⁷ For her part, Griffin “think[s] they wrote letters [and] [t]hey made phone calls.” SMF ¶ 109. But she had no knowledge of any actual phone calls, and the only “letters” she recalled were the ones (discussed in detail below) informing HANJ members of Accredo’s reduced contribution to the insurance program in 2011. SMF ¶¶ 110–12.

Greenfield also has emphasized that Bostick sometimes referred to contributions as “fees for services.” *E.g.*, Singer Decl. Ex. 37 (McAnaney Report ¶ 73). Bostick testified unequivocally that the “services” did not include referrals, SMF ¶ 113, and this is borne out by the numerous documents in which she spelled out exactly which services she had in mind—none of which mentions anything about

⁷ Greenfield points to one document that suggests that someone at HANJ was aware of one referral *from a hospital*. SMF ¶ 108. There is no evidence that this referral of an unidentified patient was in exchange for Accredo’s contributions to HANJ. *Id.*

patient referrals or recommendations, *see e.g.*, SMF ¶¶ 114–17. These “services” were things like HANJ’s successful advocacy for New Jersey legislation requiring major medical insurance to cover hemophilia treatment, which benefitted the entire hemophilia community. SMF ¶ 115.

2) *There is no evidence that HANJ made indirect referrals through HTC’s.*

The Complaint also theorized that HANJ somehow influenced patient referrals by HTC’s, some of which received grant funding from HANJ. 4AC ¶¶ 7–8, 83, 87, 99. Discovery has exposed this theory as meritless. Bostick testified without contradiction that she never told HTC’s that they should refer patients to one company over another, SMF ¶ 120, and that she had no expectation that HTC’s would refer patients to entities that had donated to HANJ, SMF ¶ 121.⁸

The HTC’s agree. Greenfield never sought to depose any representative of an HTC, but the directors and nurse coordinators of Newark Beth Israel and Robert Wood Johnson have provided declarations that flatly contradict Greenfield’s theory. They demonstrate that the HTC’s maintained and adhered to written policies emphasizing patient choice and allowed patients to choose their homecare providers.

⁸ Greenfield’s proffered expert McAnaney characterized one document as evidence that HANJ had “recommended” its donors to the HTC’s. Singer Decl. Ex. 37 (McAnaney Report ¶ 73). The document says nothing of the sort. Rather, Bostick notes that HANJ kept “our HTC’s informed as to who the H.S.I. companies are—thereby opening the door to some level of communication.” SMF ¶ 117. There is nothing illegal about that.

SMF ¶¶ 124, 128, 132, 136. The HTC's did not know how much Accredo was contributing to HANJ, and any contributions had no effect on any referrals or recommendations the HTC's made to patients. SMF ¶¶ 125–26, 129–30, 133–34, 137–38.

Against this clear record, Greenfield offers nothing but speculation. The Complaint alleges that “the individuals identified on [Complaint] Exhibit N became active patients of HHS as a result of referrals from the HTC’s that are part of the ‘contributions for referrals scheme’ alleged in this Complaint.” SMF ¶ 143. There is no evidence to support this assertion. Greenfield admitted at his deposition that he could not identify *a single patient* on Exhibit N who was referred as part of an alleged “scheme.” SMF ¶¶ 144–46. Greenfield’s friend Karen Griffin testified that, contrary to Greenfield’s theory, the New Jersey HTC's made recommendations based only on the best interests of the patients. SMF ¶ 142. She said unequivocally that “the doctors, the nurses, the social workers, nobody in the capacity as an employee at the HTC that I observed or experienced was in any way part of a conspiracy to get patients to go to any particular provider of factor.” *Id.*

b. HANJ’s “approved provider” list is not a violation of law.

When discovery put to rest the principal theories of Greenfield’s Complaint, he shifted to a new one that is not in the Complaint. He now contends that Accredo’s contributions were made in exchange for inclusion on HANJ’s list of “approved”

providers. Singer Decl. Ex. 37 (McAnaney Report ¶¶ 54–62); Singer Decl. Ex. 34 (McAnaney Dep. at 134:15–135:2). This new theory suffers from multiple fatal defects.

First, there is no evidence that Accredo made contributions for the purpose of being included on HANJ’s “approved list.” SMF ¶ 150. Not a single witness or document suggests that Accredo had such intent. This alone is dispositive of the issue.

Second, even assuming *arguendo* that Accredo made its contributions to induce HANJ to list it as an approved provider, that would not violate the AKS. Nothing in the AKS prohibits a charity from informing the public which organizations have “supported the community” by contributing to the charity. It is common practice for charities in the healthcare sphere and elsewhere to recognize their donors publicly in positive terms. *See* Singer Decl. Ex. 31 (Frumkin Report at 8); SMF ¶¶ 155–56 (citing examples). That HANJ used adjectives such as “approved” or “endorsed” in connection with these lists is not newsworthy, and Accredo is aware of absolutely no law suggesting that this sort of recognition is a federal crime under the AKS.

HANJ’s listing also does not implicate the AKS because there is no evidence that HANJ had any control over patients’ healthcare decisions. This distinguishes HANJ’s list sharply from the practices that courts have found to implicate the AKS. *See United States v. Vernon*, 723 F.3d 1234, 1254 (11th Cir. 2013) (referral source had “control” over patients’ choice of home care provider); *United States v. Patel*, 778 F.3d

607, 614 (7th Cir. 2015) (referral source was a “gatekeeper” between patients and defendant). The record demonstrates that HANJ’s conduct was analogous to the “advertising activities” and broad distribution of “promotional material[]” that do not constitute a referral because they do not “unduly influence” anyone’s judgment. *United States v. Miles*, 360 F.3d 472, 480–81 (5th Cir. 2004) (payments to a PR firm were not prohibited kickbacks because firm was not a “relevant decisionmaker”). And, as Greenfield’s expert concedes, there is no evidence that any patient actually selected Accredo because of HANJ’s list. *See* SMF ¶ 159.

Finally, as a statutory matter, HANJ’s identification of Accredo as an “approved” provider is neither a “referral” nor a “recommendation” under the AKS. Greenfield’s expert McAnaney never asserts that HANJ’s approved provider list constituted a “referral” under 42 U.S.C. § 1320a-7b(b)(2)(A), which requires that one “*refer an individual to a person* for the furnishing or arranging for the furnishing of any item or service” (emphasis added). Proof of a “referral” would require Greenfield to show that HANJ interacted with a patient or doctor to steer individual patients specifically to Accredo, and there is no such evidence. McAnaney contends that the HANJ provider list is a “recommendation” under subsection (b)(2)(B), Singer Decl. Ex. 37 (McAnaney Report ¶¶ 60, 73), but that subsection applies to one who “*recommend[s] purchasing, leasing, or ordering any good, facility, service, or item*” covered by a federal health care program, 42 U.S.C. § 1320a-7b(b)(2)(B) (emphasis added). A

“recommendation” of Accredo as a provider would not satisfy the statute because it does not direct patients to use any particular goods or services.

c. HANJ’s advocacy to its members is not a violation of law.

Greenfield’s final theory is that Accredo’s contributions to HANJ were illegal because they allegedly induced HANJ to *refrain* from disparaging Accredo to its membership. Greenfield focuses on a letter that HANJ sent to certain members in March 2011 informing them that Accredo was reducing its contributions to the insurance program. 4AC ¶¶ 87–90. The evidence is uniform that Accredo reduced its pledge because of across-the-board budget cuts, not because of anything specific to HANJ. SMF ¶ 77. Greenfield claims, however, that HANJ sent the March 2011 letter to cause Accredo patients to switch to a different provider, and that it pressured Accredo to restore its prior level of funding. *See, e.g.*, 4AC ¶¶ 85–87, 89–90.

This theory does not articulate an AKS violation. The AKS prohibits payments that are intended to induce the recipients to *make* referrals or recommendations. 42 U.S.C. § 1320a-7b(b)(2). Its plain language does not prohibit payments intended to *stop* recipients from making “disparaging” statements or, as Greenfield’s expert terms it, “*non-recommendations*.” SMF ¶ 157 (emphasis added). McAnaney could not identify any case law or regulatory guidance that would support Greenfield’s interpretation of the statute. Singer Decl. Ex. 34 (McAnaney Dep. at 309:11–15). And that interpretation would have broad, disruptive consequences: A hospital that

agreed to higher wages for its nurses in part to stop the nurses' union from picketing outside its doors, for example, would have committed an AKS violation.

In any event, the record shows that HANJ's communications with members were proper charitable advocacy. HANJ's March 2011 letter notified members that Accredo had reduced its funding, and that as a result the HANJ "insurance program [was] in jeopardy of being 'phased out' and ceasing to exist in the foreseeable future." SMF ¶¶ 78–79. The letter focused exclusively on the impact that Accredo's decision to cut funding would have on the insurance program, which the letter explained "subsidize[s] the cost of Insurance Policies to our 'uninsured' patient population." SMF ¶ 78. The letter said nothing about patients' choice of pharmacy providers. SMF ¶ 81. It requested that Accredo clients and participants in the insurance program (regardless of provider) "immediately contact Craig Mears" to request that Accredo restore the funding.⁹ SMF ¶ 80. Similarly, the evidence shows that

⁹ Elena Bostick allegedly made similar comments at a HANJ annual meeting regarding Accredo's decision to reduce funding. There is nothing in the record to indicate that these comments differed in any meaningful way from the March 2011 letters. *See* SMF ¶ 84. Similarly, HANJ sent another letter to its members acknowledging that Bioscrip had increased its contributions after learning about the "jeopardy" to the program as a result of Accredo's cuts. SMF ¶ 99. The letter requested that members contact Bioscrip and thank them. SMF ¶ 100. The only documents Greenfield has identified that refer to switching providers are internal HANJ emails between Bostick and HANJ's President and one individual HANJ Board member. *See* Singer Decl. Ex. 20 (November 2011 email chain); Singer Decl. Ex. 45 (March 2011 email chain). Bostick's comment to HANJ's President, "I think they [Accredo] need to lose one or two customers," Singer Decl. Ex. 20, at most suggests that she hoped Accredo's reduced contribution to HANJ would cost the company goodwill among its customer base and that Accredo would restore its contribution to prior levels. As discussed

Accredo’s decision to restore HANJ’s funding to its prior levels was driven by the same considerations that prompted Accredo to make its contributions in the first place: fostering goodwill in the patient community, ensuring the insurance program’s survival, and preventing HTCs from adopting “340B” programs. SMF ¶¶ 85–98.

Nothing in the AKS prohibits or seeks to deter charities from advocating to their members to petition the industry for contributions. Nothing in the AKS prohibits a contributor from responding to such advocacy by increasing (or decreasing, or leaving unchanged) its contribution amounts. These are commonplace and essential activities for charities and contributors in any sphere. *See* Singer Decl. Ex. 31 (Frumkin Report at 5–6).

Any interpretation of the AKS that would render such advocacy unlawful would not only work an unprecedented expansion of the AKS, it would also raise grave constitutional concerns. HANJ’s and Accredo’s conduct represents core expressive activity by a charitable organization and a donor, which is protected under the First Amendment. *See, e.g., Riley v. Nat’l Fed’n of the Blind of N. C., Inc.*, 487 U.S. 781, 787–88 (1988) (“[C]haritable solicitations ‘involve a variety of speech interests . . . that are within the protection of the First Amendment.’” (ellipsis in original) (citation omitted)).

above, there is nothing illegal about that. And the only specific Accredo patients discussed—the two sons of the HANJ Board Member whom she e-mailed—were not Federal Beneficiaries. Singer Decl. Ex. 45.

C. There Is No Evidence that Accredo Believed It Was Violating the Law.

Greenfield not only lacks evidence that Accredo made any payment in exchange for covered referrals, he also cannot meet his burden to prove that Accredo acted with criminal intent—“knowingly and willfully.” The AKS’s “willfulness” requirement means “the act was committed voluntarily and purposely with the specific intent to do something the law forbids; that is to say, with bad purpose either to disobey or disregard the law.” *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998) (internal quotation marks omitted); *accord, e.g., United States v. Shvets*, 631 F. App’x 91, 95–96 (3d Cir. 2015).

In addition to showing that Accredo personnel knew they were paying to induce referrals or recommendations covered by the AKS, therefore, Greenfield must establish that Accredo personnel knew and intended that their conduct was unlawful. Greenfield has identified no evidence that any Accredo employee had such criminal intent.

Before addressing the evidence on that point, it bears emphasizing that it is immaterial what Accredo personnel subjectively believed *unless* Greenfield were able to show that *under no reasonable reading of the AKS* would Accredo’s contributions to HANJ be lawful. As a matter of law, one cannot “willfully” violate the law if her conduct could be deemed legal under an “objectively [r]easonable” interpretation of the AKS—even if a court ultimately concludes that the conduct was illegal. *See Safeco*

Ins. Co. of Am. v. Burr, 551 U.S. 47, 70 n.20 (2007) (“Congress could not have intended such a result [a finding of willfulness] for those who followed an interpretation that could reasonably have found support in the courts, whatever their subjective intent may have been.”); *Long v. Tommy Hilfiger U.S.A., Inc.*, 671 F.3d 371, 377–78 (3d Cir. 2012) (“Hilfiger’s actual knowledge or intent . . . is immaterial to the objective reasonableness analysis.”); *see also Fuges v. Sw. Fin. Servs., Ltd.*, 707 F.3d 241, 251 (3d Cir. 2012); *United States ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 592–93 (E.D. Pa. 2012). Greenfield’s theory of an AKS violation—HANJ’s “approved provider” list and its so-called “non-recommendations”—does not describe any illegal conduct at all, much less a violation so clear that disputing it would be unreasonable.

In any event, there is no evidence of *subjective* criminal intent. The evidence is unequivocal that the Accredo employees who actually decided whether and how much to contribute to the HANJ insurance program did not intend to trade those contributions for (nonexistent) referrals of Federal Beneficiaries. SMF ¶¶ 85–98, 101. On the contrary, HANJ’s insurance program excluded Federal Beneficiaries and the State of New Jersey affirmatively endorsed it. *See* Statement of the Facts, *supra*, at B.2.

The Complaint alleges that “[t]here is no doubt that the management of Defendant’s [sic] knew that their actions were illegal.” 4AC ¶ 96. The sole evidence Greenfield cites as support for that allegation is his secret recording of a meeting at which “this illegal kickback scheme was openly discussed.” *Id.* But no one at that meeting said—or even suggested—that they believed Accredo’s conduct was illegal.

To the contrary, Diana Florio observed during the meeting that she believed that the State of New Jersey had “legislated that HANJ needs to pay for insurance” and “approved that [HANJ] should be funded by providers and manufacturers.” SMF ¶ 165. She commented that in “*any other* state in the country, that would be illegal . . . *only in New Jersey is that legislation legal.*” *Id.* (emphasis added).¹⁰

Greenfield also seeks to manufacture criminal intent from Accredo employees’ facetious references to HANJ as “the New Jersey mafia”—a term that witnesses testified was used “jokingly,” SMF ¶¶ 170–71, to refer to the “aggressive way [HANJ] did business,” SMF ¶ 168. Similarly, one employee testified that she had heard the term “pay to play” used to express “frustrat[ion] about some sort of strong tactics that were being taken . . . by [HANJ].” SMF ¶ 169. The speakers did not mean to suggest that Accredo’s contributions might be illegal. *Id.*

Finally, Greenfield contends that in 2010 a decision was made not to contribute additional funds to HANJ “based on concerns related to ‘compliance issues.’” 4AC ¶ 81. The only document Greenfield cites for this proposition is a private e-mail *he sent* to his friend Karen Griffin—and it says nothing of the sort. To the contrary, Greenfield explains that funding to HANJ was constrained by *budgetary* issues, not by any concern about illegality, and he unambiguously expresses support for Accredo’s contributions. SMF ¶¶ 166–67.

¹⁰ She was wrong about that, as a legal matter—in fact, this arrangement would be legal in any state—but her comment shows her innocent mental state.

* * * * *

An allegation of willful fraud—in this case, a federal crime—is a very serious matter and requires meaningful evidence, not speculation. As one court recently remarked in entering summary judgment on a relator’s AKS claim, “[a]n accusation of fraud should be made cautiously, and only when there is evidence to support it.” *Ruscher*, 2015 WL 5178074, at *23. Greenfield has mustered no such evidence.

D. There Is No Evidence that Accredo Provided Any Remuneration to Patients in Violation of the AKS.

Apart from the HANJ contributions, the Complaint prominently alleges that Accredo violated the AKS by providing items of value to patients in exchange for their continuing to use Accredo as their provider. 4AC ¶¶ 9–10, 107–13. Discovery has shown these allegations to be untrue. Greenfield himself, who supervised the employees who allegedly gave these gifts to patients, could not testify that any item was given with an illegal intent to induce a patient to use Accredo as its pharmacy, or that any patient in fact was induced. SMF ¶¶ 181, 188, 190, 204–07, 209–10. Because of this complete lack of evidence, Plaintiff appears to have abandoned this “gifts” theory of an AKS violation, and we do not discuss it further in this brief. Accredo’s Statement of Material Facts Not in Dispute recites the pertinent evidence that disproves it. SMF ¶¶ 172–210.

II. **THERE IS NO EVIDENCE THAT ACCREDO PRESENTED FALSE CLAIMS IN VIOLATION OF THE FCA.**

To sustain a claim under the False Claims Act, Greenfield must do more than prove a violation of the AKS—he must also prove that Accredo knowingly presented a false claim for government funds. *See Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 182 (3d Cir. 2001). For multiple reasons, Greenfield has no evidence of this. Most fundamentally, Greenfield has no evidence to link the charitable contributions that he contends were unlawful to *any claim* Accredo may have made to the Government. Without such a connection between the alleged AKS violation and actual claims, there is no “false claim,” and no FCA liability. This alone requires summary judgment for the Defendants.

A. **There Is No Evidence that Any Claim Was Submitted to a Government Program as a Result of an Alleged AKS Violation.**

Greenfield’s theory is that Accredo’s claims to government insurance programs for reimbursement for medicines and services provided to hemophilia patients were “false” because Accredo violated the AKS. The FCA applies on a claim-by-claim basis, and therefore Greenfield must show that actual, specific claims for reimbursement were tied to an AKS violation. *See United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007) (the False Claims Act “only prohibits a narrow species of fraudulent activity: ‘present[ing], or caus[ing] to be presented, . . . a false or fraudulent claim for payment or approval’” (alterations in original) (citation omitted)); *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of*

Utah, 472 F.3d 702, 728 n.34 (10th Cir. 2006) (affirming dismissal where relator failed to “tie any specific claim” to the alleged fraudulent scheme).

The requirement that an AKS violation be tied to a particular claim is explicit in the current version of the AKS, as amended in March 2010. The statute explicitly requires a direct causal connection between an AKS violation and a violation of the FCA: “a claim that includes items or services *resulting from* a violation of this section constitutes a false or fraudulent claim [under the FCA].” 42 U.S.C. § 1320a-7b(g) (emphasis added).

For claims submitted before the AKS was amended in March 2010, an FCA violation still depends on tying particular claims to an AKS violation. As discussed below, pre-amendment claims require Greenfield to show that Accredo affirmatively *certified* to the government that it had complied with the AKS. This Court previously held that the Complaint sufficiently alleged a certification based on Accredo’s Medicare Form 855S provider agreements, which allegedly provide that Accredo “understand[s] that payment of a claim by Medicare is conditioned upon *the claim and the underlying transaction complying with . . . the Federal anti-kickback statute.*” Op. at 25; see SMF ¶ 211 (emphasis added).¹¹ This language explicitly links any AKS violation to

¹¹ The actual certification language is not in the record; the copies of the signed Forms 855S for the relevant time period, as maintained in Accredo’s files, do not contain the pages that would have included that language. SMF ¶ 211. While Greenfield has the burden to show a false certification, we will assume, for purposes of this motion, that Accredo certified to the language alleged in the Complaint and quoted by this Court in its prior opinion.

the particular claim or transaction for which payment is requested. *See Ruscher*, 2015 WL 5178074, at *26 (“[F]or the pharmacy services to have been provided ‘*through* the payment . . . of a kickback,’ Relator would have to prove that the offer of remuneration actually induced the [nursing home] to do business with [the pharmacy]—that is, that there was a completed *quid pro quo*.” (ellipsis in original)). At the motion-to-dismiss stage, the Court recognized that Greenfield would have to develop evidence “tying defendants’ conduct to reimbursement from federal funds.” *Op.* at 25. The Court permitted Greenfield’s case to proceed to discovery because his Complaint alleged a sufficient basis to infer that such claims may exist. *Op.* at 25–27. It was incumbent on Greenfield, in discovery, to substantiate that allegation with actual evidence of false claims. There is no such evidence.

Greenfield has no evidence of a connection between an alleged AKS violation and any claim for government funds. There is no evidence that any government-insured patient (or, for that matter, any patient of any kind) purchased any prescription from Accredo because of Accredo’s contributions to HANJ. His experts proffered no analysis purporting to show such a linkage. Greenfield’s damages expert, Albert Palentchar, merely undertook to add up federal payments for Accredo hemophilia patients in New Jersey for the period January 1, 2008 through December 31, 2012. *Singer Decl. Ex. 74* (Palentchar Amended Report).¹² Palentchar did not

¹² Accredo disagrees with this measure of damages, but that issue is outside the scope of this motion.

purport to opine that any federal payments derived from Accredo's charitable contributions to HANJ. *Id.* Greenfield admitted that he could not identify any patients whose referral was induced by Accredo's contributions to HANJ. *See* SMF ¶¶ 104, 144–46. On the contrary, the evidence suggests that patients used Accredo because it provided high quality services to its customers. *See* SMF ¶¶ 25–29. Even Bostick, despite her displeasure with Accredo's reduction in funding, admitted that “[HANJ] members on their service are very happy.” SMF ¶ 30.

Absent evidence that even a single federally-insured patient purchased Accredo's products and services because of an AKS violation, Greenfield has not met his burden of showing that Accredo submitted claims that were false.

B. For Claims Submitted Before March 2010, There Is No Evidence that Accredo Certified Its Compliance with the AKS as a Condition of Payment.

Even if Greenfield could show that a claim Accredo submitted was tied to an AKS violation—which, as discussed above, he cannot—that would not necessarily make the claim “false.” A violation of law typically does not make a claim “false” for FCA purposes unless the presenter certifies to the government that it has *not* violated the law.

Different standards apply to claims submitted before and after the AKS was amended in March 2010. Under the current version of the AKS, a claim for products or services resulting from an AKS violation is automatically false for FCA purposes.

42 U.S.C. § 1320a-7b(g). But under the *pre*-March 2010 statute, which governs the

majority of the claims in this case,¹³ a separate certification is required, as this Court has found. *See* Op. at 23.

Regarding many of Accredo's claims for reimbursement, there is no evidence of any certification of any kind. Greenfield has identified no certifications submitted to Medicaid, Tricare, or Medicare Part C ("Medicare Advantage"). SMF ¶ 212. Thus, any claims made to these programs before March 2010 cannot be "false" as a matter of law.

Regarding Medicare Part B, Greenfield has identified the certifications in Accredo's Form 855S provider applications. SMF ¶ 211. These forms were submitted at the outset of Accredo's program participation, not with the individual claims. *Id.* Greenfield's case thus depends on a theory of "*implied* certification," meaning that the defendant previously committed to comply with a law as a condition of payment. *See United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 307 (3d Cir. 2011) (emphasis added) (discussing express and implied forms of certification). The Supreme Court is currently considering whether "implied certification" states a valid theory of legal falsity under the FCA. *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 780 F.3d 504 (1st Cir.), *cert granted in part*, 136 S.

¹³ The 2010 amendment is not retroactive and applies only to claims for reimbursement submitted to the government after its March 2010 effective date. *Wilkins*, 659 F.3d at 311 n.19.

Ct. 582 (2015). If the Supreme Court rejects the doctrine of implied certification, this Court may dismiss Greenfield's pre-March 2010 claims on that basis alone.

C. There Is No Evidence that Accredo "Knowingly" Made a False Claim.

In addition to proving that Accredo made a false claim, Greenfield must show that Accredo acted "knowingly." 31 U.S.C. § 3729(a)(1). "[K]nowingly" means "actual knowledge of the information," "deliberate ignorance" or "reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1).

Importantly, Greenfield must show that a *specific individual* at Accredo had the required knowledge. There is no such thing as "aggregate" corporate guilty knowledge. *See Aetos Corp. v. Tyson Foods, Inc. (In re Tyson Foods, Inc. Sec. Litig.)*, 155 F. App'x 53, 57 (3d Cir. 2005) (citing *Southland Sec. Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 366 (5th Cir. 2004) (rejecting that "the collective knowledge of all the corporation's officers and employees acquired in the course of their employment" could satisfy scienter)); *United States v. Sci. Apps. Int'l Corp.*, 626 F.3d 1257, 1275 (D.C. Cir. 2010) ("We know of no circuit that has applied the 'collective knowledge' theory to the FCA."); *United States v. Educ. Mgmt. Corp.*, 871 F. Supp. 2d 433, 452 (W.D. Pa. 2012) ("[S]cienter may not be based on a 'collective knowledge' theory 'by piecing together scraps of 'innocent' knowledge held by various corporate officials, even if those officials never had contact with each other or knew what others were doing in connection with a claim seeking government funds.'" (citation omitted)). Because

Greenfield’s claim of “falsity” depends on a violation of the AKS, he must show that a specific person acting for Accredo both knew of the AKS violations *and* knew that the violations tainted Accredo’s reimbursement claims. *Ruscher*, 2015 WL 5178074, at *29.

As discussed in Part I, there is no evidence that any person knew that Accredo was violating the AKS. Nor is there evidence of any single person who knew or recklessly disregarded that Accredo was submitting claims to the government that were false because of AKS violations. For this reason, too, Greenfield cannot prove his FCA case.

D. There Is No Evidence that Accredo Used a “False Statement or Record” To Get a Claim Paid.

Count 2 of the Complaint charges a claim under FCA subsection (a)(2), which imposes liability for making a “false statement or record” in connection with a claim to the Government. 31 U.S.C. § 3729(a)(2).¹⁴ Summary judgment should be granted on this count for all of the same reasons stated above, and also because there is no evidence of any “false record or statement”—which must be separate from the claim itself, or else subsection (a)(2) would be entirely duplicative of subsection (a)(1). *See*

¹⁴ Until 2009, subsection (a)(2) applied to any person who “knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.” In 2009, the statute was amended, and codified as 31 U.S.C. § 3729(a)(1)(B), to impose liability on any person who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” The arguments in this Brief apply equally to the pre- and post-amendment versions.

United States ex rel. Willard v. Humana Health Plan of Tex. Inc., 336 F.3d 375, 380 (5th Cir. 2003); John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.01[D] (4th ed. 2010).

CONCLUSION

Summary judgment should be granted for Accredo.

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Respectfully submitted,

/s/ Robert M. Goodman

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